vacuum to draw blood for subsequent reinfusion.

(b) *Classification.* Class I (general controls). The manual device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60639, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.9145 Processing system for frozen blood.

(a) *Identification.* A processing system for frozen blood is a device used to glycerolize red blood cells prior to freezing to minimize hemolysis (disruption of the red cell membrane accompanied by the release of hemoglobin) due to freezing and thawing of red blood cells and to deglycerolize and wash thawed cells for subsequent reinfusion.

(b) *Classification.* Class II (performance standards).

[45 FR 60639, Sept. 12, 1980]

§ 864.9160 Blood group substances of nonhuman origin for in vitro diagnostic use.

(a) *Identification.* Blood group substances of nonhuman origin for in vitro diagnostic use are materials, such as blood group specific substances prepared from nonhuman sources (e.g., pigs, cows, and horses) used to detect, identify, or neutralize antibodies to various human blood group antigens. This generic type of device does not include materials that are licensed by the Center for Biologics Evaluation and Research of the Food and Drug Administration.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60640, Sept. 12, 1980, as amended at 53 FR 11253, Apr. 6, 1988; 63 FR 59225, Nov. 3, 1998]

§ 864.9175 Automated blood grouping and antibody test system.

(a) *Identification.* An automated blood grouping and antibody test system is a device used to group erythrocytes (red blood cells) and to detect antibodies to blood group antigens.

(b) *Classification.* Class II (performance standards).

[45 FR 60641, Sept. 12, 1980]

§ 864.9185 Blood grouping view box.

(a) *Identification.* A blood grouping view box is a device with a glass or plastic viewing surface, which may be illuminated and heated, that is used to view cell reactions in antigen-antibody testing.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60641, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.9195 Blood mixing devices and blood weighing devices.

(a) *Identification.* A blood mixing device is a device intended for medical purposes that is used to mix blood or blood components by agitation. A blood weighing device is a device intended for medical purposes that is used to weigh blood or blood components as they are collected.

(b) *Classification.* Class I (general controls). The manual device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60642, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.9205 Blood and plasma warming device.

(a) *Nonelectromagnetic blood or plasma warming device*—(1) *Identification.* A nonelectromagnetic blood and plasma warming device is a device that warms blood or plasma, by means other than electromagnetic radiation, prior to administration.

(2) *Classification.* Class II (performance standards).

(b) *Electromagnetic blood and plasma warming device*—(1) *Identification.* An electromagnetic blood and plasma warming device is a device that employs electromagnetic radiation (radiowaves or microwaves) to warm a bag or bottle of blood or plasma prior to administration.

(2) *Classfication.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 864.3.

[45 FR 60642, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987]

§ 864.9225 Cell-freezing apparatus and reagents for in vitro diagnostic use.

(a) *Identification.* Cell-freezing apparatus and reagents for in vitro diagnostic use are devices used to freeze human red blood cells for in vitro diagnostic use.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60643, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.9245 Automated blood cell separator.

(a) *Identification.* An automated blood cell separator is a device that automatically removes whole blood from a donor, separates the blood into components (red blood cells, white blood cells, plasma, and platelets), retains one or more of the components, and returns the remainder of the blood to the donor. The components obtained are transfused or used to prepare blood products for administration. These devices operate on either a centrifugal separation principle or a filtration principle. The separation bowls of centrifugal blood cell separators may be reusable or disposable.

(b) *Classification of device operating by filtration separation principle.* Class II (special controls). The special controls for the device are that the manufacturer must file an annual report with FDA for 3 consecutive years. Each annual report must include the following:

(1) A summary of adverse donor reactions reported by the users to the manufacturer that do not meet the threshold for medical device reporting under part 803 of this chapter;

(2) Any change to the device, including but not limited to:

(i) New indications for use of the device;

(ii) Labeling changes, including operation manual changes;

(iii) Computer software changes, hardware changes, and disposable item changes, e.g., collection bags, tubing, filters;

(3) Equipment failures, including software, hardware, and disposable item failures, e.g., collection bags, tubing, filters.

(c) *Classification of device operating by centrifugal separation principle.* Class III (premarket approval).

(d) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (c) of this section. See § 864.3.

[45 FR 60645, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987; 68 FR 9532, Feb. 28, 2003]

§ 864.9275 Blood bank centrifuge for in vitro diagnostic use.

(a) *Identification.* A blood bank centrifuge for in vitro diagnostic use is a device used only to separate blood cells for further diagnostic testing.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60645, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.9285 Automated cell-washing centrifuge for immuno-hematology.

(a) *Identification.* An automated cell-washing centrifuge for immuno-hematology is a device used to separate and prepare cells and sera for further in vitro diagnostic testing.

(b) *Classification.* Class II (performance standards).

[45 FR 60646, Sept. 12, 1980]

§ 864.9300 Automated Coombs test systems.

(a) *Identification.* An automated Coombs test system is a device used to detect and identify antibodies in patient sera or antibodies bound to red cells. The Coombs test is used for the diagnosis of hemolytic disease of the newborn, and autoimmune hemolytic anemia. The test is also used in crossmatching and in investigating